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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,720	07/17/2000	Martin Nicklin	MSA-021.01	7893

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/617,720	NICKLIN ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12, 27, 28, 30, 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 27, 28, 30, 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1a. Receipt of Applicants' after final amendment and arguments filed on 20 January 2004 is acknowledged.

Status of Claims:

1b. Claims 1-11, 13-26, 29, 31 have been canceled, claims 12, 32, 33, 34 and 36 have been amended. Thus claims 12, 27-28, 30, 32-37 are pending and under consideration.

2a. Upon further consideration and search, the examiner has decided to withdraw the finality of the previous office action (mailed on 20 October 2003). PROSECUTION IS HEREBY REOPENED. Also the indicated allowability of 27, 28, 30 is withdrawn.

3. The following previous objections and rejections are withdrawn in light of Applicants' amendment filed on 01/20/04:

(I) All of the rejections and objections made against cancelled claims 29 and 31 are withdrawn.

(II) The objection to the specification for not providing accession numbers is withdrawn.

(III) The objection to claims 12, 26, 32 and 33 for reciting non-elected SEQ ID Nos is withdrawn.

(IV) The rejection of claim 33 made under 35 U.S.C. 112, second paragraph, for not reciting hybridization conditions is withdrawn.

(V) The rejection of claim 33 made under 35 U.S.C. 112, first paragraph, for introducing new matter is withdrawn. Applicants' explanation that SEQ ID Nos:54-64 correspond to EST sequences recited in original claims 18 and 19 is persuasive.

Maintenance of Rejections:

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4a. The rejection of claims 32 and 33 made under 35 U.S.C § 102(b) as being anticipated by Bentos et al (28 August 1998), is maintained.

Applicants argue that Bentos et al does not disclose a complement of the nucleic acid of SEQ ID NO:1, but discloses a nucleic acid that shares identity to SEQ ID NO:1, therefore, Bento's nucleic acid would not be expected to hybridize to instant SEQ ID NO:1. Thus, Applicants conclude that the nucleic acid disclosed by Bentos et al cannot anticipate claim 32.

Applicants are correct in that a nucleic acid that would hybridize with the nucleic acid of SEQ ID NO:1 would not share a region of identity with SEQ ID NO:1, but would be a sequence that is complementary to SEQ ID NO:1. However, the complement of the nucleic acid disclosed by Bentos et al, which easily identifiable once the target nucleic acid is known, would be expected to hybridize to instant nucleic acid of SEQ ID NO:1.

Therefore, Bentos et al reference anticipates the instant claims 32 and 33 in the absence of any evidence to the contrary.

Claim rejections-35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4b. Claims 32-37 stand rejected under 35 U.S.C § 102(e) as being anticipated by Ford et al (U.S Patent 6,294,655), for reasons of record set forth in the office action mailed on 10 October 2003.

Applicants argue that the nucleic acid disclosed by Ford et al would not be expected to hybridize to instant SEQ ID NO:1, since it shares regions of identity to SEQ ID NO:1. Applicants are correct, however, Ford et al reference does not only disclose the nucleic acid which shares 86.6% identity to instant SEQ ID NO:1, but also discloses the complement of said nucleic acid, (see column 55). Therefore, the complement disclosed by Ford et al would be expected to hybridize to instant SEQ ID NO:1.

Applicants further argue that instant claim 33 expressly states that the claimed nucleic acid does not consist of SEQ ID NO:55, which is GenBank Accession number AI040890, which is asserted to be the Ford et al sequence. This is not found persuasive, because SEQ ID NO:8 disclosed by Ford et al consists of 7605 bases while the Genbank nucleic acid Accession number AI040890 consists of 473 bases. Thus, instant claim 33 does not exclude the Ford et al nucleic acid.

Therefore, the Ford et al reference anticipates the instant claims 32-37 in the absence of any evidence to the contrary.

New Rejections:

Claim Rejections - 35 U.S.C. § 101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 12, 27-28, 30 and 32-37 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Instant claims are directed to an isolated nucleic acid molecule consisting of the nucleic acid sequence set forth SEQ ID NO1, 2 or 3, an isolated nucleic acid which hybridizes to said nucleic acid, a vector comprising said nucleic acid, and a recombinant host cell comprising said vector.

The specification describes the claimed nucleic acid as being human genes encoding novel proteins, which have sequence homologies with the interleukin-l receptor antagonist protein (IL-1ra) as well as interleukin-1 (IL-1), (see top of page 4). The specification refers to the protein of the instant invention as IL-IL1. The specification discloses that the human IL-IL1 of the instant invention shares 47% overall identity to human IL-Ira 47% and 27% overall identity to human IL-1 beta polypeptide, (see page 14, second paragraph). Instant specification asserts that whether the IL-IL-1 polypeptide of the instant invention has biological activities similar to IL-1 or to IL-1ra can be

determined by using assays that are well known in the art. For example, the ability of the IL-ILI protein of the instant invention to activate the expression of interleukin-6 gene expression in human skin fibroblasts is indicative of an IL-1β like IL-I agonist activity. In contrast, the ability of recombinant IL-ILI polypeptides to interfere with IL-1α or 1L-1β induced activation of interlellkin-6 gene expression is indicative of IL-Ira-like IL-1 antagonist activity, (see page 52). The instant specification also asserts that therapeutics of the present invention include those which antagonize interleukin-I dependent disorders of the human placental including intraventricular hemorrhage, neonatal white matter damage and subsequent cerebal palsy, and the occurrence of premature low birth weight deliveries, (page 105).

However, the instant specification demonstrates that the IL-IL1 polypeptide of the instant invention does not stimulate or inhibit IL-6 gene expression, thus it has no agonistic or antagonistic IL-1 activity, (see pages 120-121). The instant specification concludes that the IL-IL-1 polypeptide has no direct effect on the IL-1 system. Accordingly, the claimed invention cannot be used to treat diseases that are treatable with an IL-1 antagonist or IL-1 agonist , since the IL-IL-1 polypeptide of the instant invention does not have any IL-1 antagonistic or agonistic activity.

Therefore, since the instant specification demonstrates that the IL-IL-1 polypeptide of the instant invention does not have an activity similar to IL-1 or to IL-ra, and since the specification discloses no information regarding the physiological significance, functional characteristics or any conditions that involve the nucleic acids of

SEQ ID Nos:1, 2 or 3, or the encoded polypeptide, the claimed invention lacks specific and substantial asserted utility or a well-established utility.

5b. Claims 12, 27-28, 30 and 32-37 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification discloses that the IL-IL-1 polypeptide has no direct effect on the IL-I system, therefore, this polypeptide cannot be used to treat or diagnose disorders that involve IL-1. Accordingly, there is no specific and substantial asserted utility or well established for the claimed invention. Although the specification describes the structure of the IL-IL-1 polypeptide of the instant invention and discloses that it is homologous to IL-1 andIL-1ra, the skilled artisan would not know how to use said polypeptide, because Applicants do not provide any information regarding biological activity or physiological significance of said polypeptide. Instant specification also fails to establish a correlation between the claimed invention and a disease state.

5c. Claim 35 recites "a host cell.....", however the claimed invention is directed to non-statutory subject matter, because the claim encompasses the host cell as it occurs in nature. Since the Applicants do not intend to claim a naturally occurring product, it is suggested that he claim be amended to recite "an isolated" before host cell to show the hand of man.

Claim rejections-35 U.S.C. § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 35 recites "a host cell comprising the vector *or* claim 34", which appears to be a typographical error, because "of" rather than "or" should be recited before claim 34. Appropriate correction is required.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner

Art Unit 1647
19 June 2004

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